

REMARKS/ARGUMENTS

Claims 2 - 3, 6, 25 - 31, 33 - 34, 37, and 45 - 48 are pending. Claims 1, 4 - 5, 7 - 24, 32, 35 - 36 and 38 are canceled by way of this amendment. Claims 2, 25, 31, 33, 37 and 45 are amended solely in an effort to advance prosecution, in view of the Examiner's remarks concerning enablement. Applicants reserve the right to present claims directed to additional neoplasms in a timely filed continuing application.

Claim 45 is amended to reintroduce the word "inhibitor", which was inadvertently removed within the Amendment filed November 9, 2007. No new matter is introduced by way of these amendments.

I. Improper Finality of Office Action

Applicants respectfully traverse the finality of the Office Action dated December 30, 2008. This Action was a second Office Action following a Request for Continued Examination. MPEP 706.07(a) provides

Under present practice, second or any subsequent actions on the merits shall be final, *except where the examiner introduces a new ground of rejection* that is neither necessitated by applicant's amendment of the claims, nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p). . . Furthermore, a second or any subsequent action on the merits in any application or patent undergoing reexamination proceedings *will not be made final if it includes a rejection, on newly cited art*, other than information submitted in an information disclosure statement filed under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p), *of any claim not amended by applicant* or patent owner in spite of the fact that other claims may have been amended to require newly cited art. . .

[Emphasis added]

Lane, *et al*, US Patent Application Publication No. US 2004/0147541 A1 ("Lane") was newly cited by the Examiner, and not previously disclosed by

Applicants in an IDS. Further, Applicants note that corresponding International Publication No. WO 02/066019 (publication of international application from which Lane stems) was first identified as document "F2" in the IDS filed June 2, 2004, which is within the period provided under 37 CFR 1.97(b)(3). Further, Applicants' last response, filed August 28, 2008, contained only a single amendment to claim 35 and presented new claim 49. Claims 1-38 and 45-47 were not amended therein.

In view of the above, the finality of the December 30, 2008 Office Action is premature. Applicants respectfully request that the finality be withdrawn, and a new non-final Action be issued to address any new rejections.

II. 35 USC 102(b)

Claims 1 - 38 and 45 - 49 have been rejected under 35 USC 102(b) as being anticipated by Lane et al, US Patent Application Publication No. US 2004/0147541 A1 ("Lane")¹.

Applicants respectfully disagree. 35 USC 102 reads that a person shall be entitled to a patent unless

. . . (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, . . .

Lane was published July 29, 2004, *after* the filing date of this application (March 1, 2004) and of the priority application (March 5, 2003). Lane is not available as a reference under 35 USC 102(b). Accordingly, the Examiner is respectfully requested to reconsider and withdraw this ground of rejection.

¹ Applicants note for clarity that CCI-779 is rapamycin 42-ester with 3-hydroxy-2-(hydroxymethyl)-2-methylpropionic acid, rather than "42-O-(2-hydroxy)ethyl rapamycin", as noted at page 3 of the December 30, 2008 Office Action.

III. 35 USC 112, first paragraph

Claims 1 - 5, 7 - 38, and 45 - 48 are rejected under 35 USC 112, first paragraph, for not being enabling for other than the treatment of breast cancer).

Applicants respectfully disagree. However, solely to advance prosecution of the application (and reserving the right to present canceled subject matter within a timely filed continuing application), Applicants have amended the claims to provide that the neoplasm is breast cancer. This is consistent with the Examiner's acknowledgement of enablement for this subject matter (December 30, 2008 Office Action at page 6, text of 35 USC 112 rejection).

With respect to claims 30 and 48 (antineoplastic combinations), Applicants respectfully assert that the claims are enabled. MPEP §2164.01(b) provides that

As long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. 112 is satisfied. In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

The claims are directed to a combination of CCI-779 or 42-O-(2-hydroxy)ethyl rapamycin and an aromatase inhibitor, which possesses utility in cancer therapy². Applicants have described how to make the claimed combinations, *i.e.*, in the specification throughout (page 4, line 21, *et seq.*) Further, one of skill in the art will readily be able to prepare the claimed combinations.

Accordingly, the Examiner is respectfully requested to reconsider and withdraw this ground of rejection.

IV. Information Disclosure Statement Acknowledgement

Applicants note that the Examiner has not acknowledged disclosure of US Pat. No. 6,511,986 (document "US31") identified in the Fourth Information

² The Examiner has acknowledged that methods of treating breast cancer with the claims combinations are enabled.

Appln No. 10/790,488
Response to OA dated December 30, 2008

Disclosure Statement (filed August 28, 2008). Kindly acknowledge disclosure of this document on the form provided as part of the IDS. A copy of the IDS form listing this document is attached for the Examiner's convenience.

The Director is hereby authorized to charge any deficiency in any fees due with the filing of this paper or during the pendency of this application to Deposit Account Number 08-3040.

Respectfully submitted,
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Dated: 6/9/2009

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